

52 line 1

Please replace the paragraph beginning at page ~~51~~, line ~~23~~, with the following rewritten paragraph:

Jm 6/11/06

-- Landing 214 of anvil 210 is also useful feature when the anvil is used in combination with a compression plate apparatus or some of the means for joining a portion of the first vessel that defines the first vessel opening to a portion of a second vessel that defines a second vessel opening such that the first vessel and the second vessel are anastomosed together and are in fluid communication. As noted above, landing 214 is essentially the surface of the cylindrical portion of anvil 210. When an anvil with a spherical engaging end and cylindrical landings such as anvil 210 is used with a compression plate apparatus such as apparatus 300 then the spherical engaging end can extend through first compression plate opening 320a and into the apparatus while landing 214 abuts the wall of blood vessel 20 against holding tabs 314a. The tolerance between landing 214 and holding tabs 314a is such that landing 214 initially rests against holding tabs 314a until sufficient force is applied to pull anvil 210 through compression plate apparatus 300. As shown in FIGS. 4B-4C and FIGS. 12D-12E, landing 214 assists in the eversion process before anvil 210 is pulled through the compression plate apparatus. More particularly, landing 214 enables the portion 26 defining the first vessel opening 24 to be everted as everted portion 56 of graft vessel 50 is pushed against portion 26. As everted portion 56 pushes against portion 26, portion 26 curls up and over holding tabs 314a. This process preferably fully everts portion 26, however, satisfactory results are obtained even if portion 26 is only partially everted. --

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Please replace the paragraph beginning at page 52, line 21, with the following rewritten paragraph:

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-- FIG. 7C depicts an anvil 210c that has a spherical engaging end 212c opposite from a tapered terminal end. As explained below, many features described herein in reference to an intraluminally positioned anvil apparatus also relate to an externally directed anvil apparatus. As shown in FIGS. 16A-16E, FIGS. 17A-17C, FIGS. 18A-18B, FIGS. 19A-19B, an anvil 210 may be inserted through a wall of a blood vessel at an insertion opening that has been selected as an anastomosis site and positioned in a lumen of the first vessel with the anvil pull 230 extending through the insertion opening of the blood vessel. Note that such use may require some modifications. For example, use of an anvil with a tapered end such as tapered end 218c minimizes the size needed for the insertion opening since the vessel wall can stretch as the taper of the anvil increases. --

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Please replace the paragraph beginning at page 54, line 14, with the following rewritten paragraph:

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-- Distal end 142' may be adapted for providing a lateral exit for piercing end 232' of anvil pull 230'. Distal end 142' may have a deflecting surface and a lateral aperture that guides piercing end 232' towards the intima of receiving blood vessel 20. Because piercing end 232' is very sharp, such deflecting surface is preferably a puncture and abrasion resistant surface. In addition, distal end 142' may have an appropriate marker for imaging the orientation of the aperture at distal end 142 and/or the position of distal end 142 itself. Such radio-opaque markers can be any of the radio-opaque markers known in the practice of angiography. Similarly, all of

Please replace the paragraph beginning at page 60, line 1, with the following rewritten paragraph:

-- Compression plates 310a-b are provided in the exemplary embodiment shown in FIG. 3A with a plurality of holding tabs 314a-b respectively protruding from opposing anastomosis sides 322a and 322b of compression plates 310a-b. More particularly, holding tabs 314a-b extend respectively from rings 312a-b of compression plates 310a-b. Holding tabs 314a-b are intended to hold the everted contours of the structures being anastomosed. Each one of holding tabs 314a-b has a base that integrally extends from the anastomosis side of the ring 312a-b of the corresponding plate at 313a-b and that terminate at rounded tips 315a-b. Distal tips 315a-b are preferably rounded as shown to minimize the potential for penetration. However, in some embodiments, the distal tips may be pointed, for example, when holding a graft vessel. Holding tabs 314a-b are typically rather rigid, however, they may also be designed to elastically bend in such a way that the distal tips of such holding tabs slightly swing about their respective bases. Such a bending action may be caused by the displacement through any of openings 320a-b defined by holding tabs 314a-b, more particularly the distal tips 315a-b of holding tabs 314a-b. -

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Please replace the paragraph beginning at page 60, line 15, with the following rewritten paragraph:

-- The number of holding tabs and their spacing may be varied as needed as long as the portions of the vessels defining the vessel openings can be maintained in an everted orientation. For example, the plurality of holding tabs may include sixteen holding tabs as shown in FIG. 3A.

However, smaller amounts may also be utilized, for example there may be only six to ten holding tabs. --

Please replace the paragraph beginning at page ~~60~~<sup>61</sup>, line ~~25~~<sup>5</sup>, with the following rewritten paragraph:

-- Each of the holding tabs shown in the embodiment depicted in FIG. 3A is attached at its base 316a-b at the inner peripheries 313a-b of rings 312a-b. However, the bases 316a-b may also extend from other locations of the rings. For example, the bases 316a-b may extend from rings 312a-b between the outer peripheries 311a-b and the inner peripheries 313a-b or perimeter on the anastomosis sides 322a-b of each annular compression plate. --

Please replace the paragraph beginning at page 61, line ~~5~~<sup>11</sup>, with the following rewritten paragraph:

-- Although, it is not necessary for the holding tabs in each compression plate to be oriented relative to the holding tabs in the other compression plate in a mating configuration, it is preferred. When referring to the relative configuration of the holding tabs in opposing compression plates, the terms "mating or mated configuration" describe a configuration in which each one of the holding tabs in a compression plate can generally fit in the space between two neighboring holding tabs in the opposing compression plate when such compression plates are close enough. As shown by the phantom lines in FIG. 3A, holding tabs 314b are offset from holding tabs 314a such that as the plates are brought towards each other each holding tab 314b is positioned opposite from the spaces between holding tabs 314a in a mated configuration. When the compression plates are brought together just close enough for the tips 315a-b to be in the same plane, then the everted tissue is held in place and the anastomosis is secure. Failure to bring the compression plates sufficiently close together such that the tips 315a-b are significantly

close together risks the potential loss of the tissue that has been captured and everted onto holding tabs 314a-b. Note that each holding tab 314b is shown just barely entering into an opposing space between adjacent holding tabs 314a. Of course, the compression plates may be designed for further compression such that holding tabs 314b further enter the space between adjacent holding tabs 314a. However, the compression plates are preferably designed such that the plates are brought together without penetrating blood vessel 20 or graft vessel 50. Note that guides 330 maintain the orientation of the compression plates so that the respective teeth have the preferred mating configuration. --

Please replace the paragraph beginning at page 65, line 9, with the following rewritten paragraph:

-- When second compression plate is formed from plastic, the desired frictional engagement is generally achieved whether guides 330 are made from metal or plastic. However, when second compression plate is formed from metal and the guides are also metal, it is preferable to utilize an alternative frictional engagement. For example, FIG. 5A shows compression plate apparatus 300 with an optional holding ring 340 that has a friction coupling with guides 330 through its guide orifices 346. Holding ring 340 is provided with opening 348 whose internal diameter is preferably at least equal to that of the opening 320b of compression plate 310b. The frictional engagement of holding ring 340 with guides 330, like the frictional engagement described above for guide apertures 334 with guides 330, is such that expansion of the anastomosed structures cannot separate compression plates 310a-b with respect to each other when holding ring 340 is in contact engagement with exterior side 324b of compression plate

310b opposite to its anastomosis side 322b. The holding ring may, for example, be formed from nylon. --

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Please replace the paragraph beginning at page 65, ~~line 22~~, with the following rewritten paragraph:

-- Other embodiments of this invention are provided with different frictional engagements that are designed to prevent compression plate 310b from significantly moving away from compression plate 310a. For example, guides 330" of compression plate apparatus 300" in FIG. 13 have barbs 336. These frictional engagement configurations described above enable the compression plates to be approached to a desired relative separation and maintained at that separation. This feature also permits the control of the pressure applied to the everted tissue of the anastomosed structures and the compression of the plates in stages so that they are approximated in a controlled manner. --

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Please replace the paragraph beginning at page 66, line 4, with the following rewritten paragraph:

-- These frictional engagements are all examples of means for locking the compression plates together. More particularly, guides that engage appropriately sized apertures 334 of second compression plate 310b for frictional engagement, a holding ring 340 that has guide orifices 346 sized to fractionally engage a guide 330, and guide barbs 336 for irreversible advancement of second compression plate 310b as the guide extends through guide apertures 334 of second compression plate 310b are all examples of means for locking the compression plates

together. Note that when the frictional engagement is achieved through reliance on guides that extend from a first compression plate and that pass through appropriately sized apertures in the second compression plate then it can be said that the first compression plate and the second compression plate have means for locking the compression plates together. An advantage of such locking means that are part of the first and second compression plates is that it is not necessary to separately attach the locking means to the compression plate apparatus after it has been used to anastomose the vessels. --

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Please replace the paragraph beginning at page 67, line 19, with the following rewritten paragraph:

-- First compression plate 310a' has a ring 312a' with an inner periphery 313a' and an outer periphery 311a'. A plurality of holding tabs 314a' extend from ring 312a'. Like holding tabs 314a, each holding tab 314a' has a base 316a' and terminate at a distal rounded tip 315a'. The base of each tab is preferably integral, as shown, with ring 312a'. Each holding tab 314a' extends at its base from ring 312. More particularly, each holding tab 314a' extends from inner periphery 313a' from exterior side 324a' toward anastomosis side 322a'. --

68 5 SM 6/16/06  
Please replace the paragraph beginning at page 67, line 25, with the following rewritten paragraph:

-- Holding tabs 314a' extend either perpendicularly from ring 312a' of first compression plate 310a' or curve inward from exterior side 324a' of ring 312a' of first compression plate 310a' such that distal rounded tips 315a' of holding tabs 314a' are perpendicularly oriented relative to exterior side 324a' of ring 312a' of first compression plate 310a'. Like holding tabs 314a,

holding tabs 314a' may have varying configurations and various numbers of holding tabs may be utilized. --

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Please replace the paragraph beginning at page 71, line 12, with the following rewritten paragraph:

-- FIG. 12F depicts portion 26 fully everted on holding tab 314a' such that portion 27 opposite from rounded tip 315a' is held in contact with the portion 57' of vessel 50 opposite from rim 368. After compression plate apparatus 300' has been compressed to join portion 26 of blood vessel 20 that defines first vessel opening 24 to portion 56' of second vessel 50' that defines graft vessel opening 54' then first vessel 20 and second vessel 50 are anastomosed together and are in fluid communication. Anvil apparatus 200 and cutter 400 have been removed upon the completion of the procedure through lumen 58 of graft vessel 50. More particularly, once the anastomosis is completed then anvil pull 230 is pulled so that it draws anvil 210 through openings 320a, 320b' and 372 of compression plate apparatus 300' such that anvil apparatus 200 is removed along with cutter 400 through lumen 58'. FIG. 12G depicts vessel 20 anastomosed to vessel 50' after attachment actuation device 600' has been removed. --

75  
SM 6/16/06  
Please replace the paragraph beginning at page 74, line 10, with the following rewritten paragraph:

-- These cutting devices disclosed herein are all examples of cutting means for forming an opening in the wall of the first vessel at the anastomosis site through engagement with the anvil of an anvil apparatus as an engaging means holds the anvil pull of the anvil apparatus after



receiving the anvil pull through the cutting means. The cutting devices engage an anvil to form the vessel opening in any suitable manner. For example, the cutting device may be pushed against the anvil, the anvil may be pulled against the cutting device, or both may simultaneously occur such that the anvil is pulled as the cutting device pushes against the anvil. --

76 4  
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Please replace the paragraph beginning at page ~~75~~, line ~~3~~, with the following rewritten paragraph:

-- It is not always necessary for cutter 400 to have a centering core or for other cutting devices to have a centering core or a centering conduit. When the engaging end of the anvil is spherical and the cutter is spherical and configured such that it permits part of the spherical engaging end of the anvil to be positioned in cutter chamber 420 then the cutter self centers on the spherical engaging end. The entire cutting device need not be hollow. For example, cutting device 400'' has a recess 428 at its cutting end that is deep enough to permit the engaging end of anvil 200d' to extend into recess 428 so that anvil 200d' may be centered and seated. Accordingly, the cutting end is preferably adapted to receive a portion of the engaging end into the cutter to enable the engaging end to self center and be seated. Also, the engaging end is preferably convex and more preferably spherical. --

76 24  
SM 6/16/06  
Please replace the paragraph beginning at page ~~75~~, line ~~22~~, with the following rewritten paragraph:

-- A spring-biased cutter also enables the cutter to be pushed back by anvil 210 to allow anvil 210 to further distend the wall of vessel 20 as shown in FIGS. 4A-4B, FIGS. 6D□6E,

FIGS. 12C-12E, FIGS 15B-15C and FIGS. 16D-16E. As anvil 210 pushes cutter 400 through vessel 20, anvil 210 causes cutter 400 to retract, however, increasing resistance is encountered as spring 460 becomes further compressed. So cutter 400 applies increasing amounts of pressure to vessel 20 as anvil 210 continues to stretch the wall of vessel 20 into compression plate apparatus 300. By optimizing features such as the tension of the spring and the length of the cutter, vessel 20 is distended far enough into compression plate apparatus 300 to leave sufficient lengths of the vessel in the compression plate apparatus for capturing in the subsequent eversion process onto holding tabs 314a. It has been found that about 17 -18lbs or about 20 lbs is generally required to form the anastomosis fenestra. --

Please replace the paragraph beginning at page <sup>77</sup>~~76~~, line <sup>9</sup>~~7~~, with the following rewritten paragraph:

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-- The gradual increase in pressure also serves to assist a spherical engaging end 212 of anvil 210 to self center on cutter 400. If anvil 210 is initially misaligned on cutter 400 then the gradual increase in pressure causes the anvil to be gradually drawn to center as the spherical engaging end 212 is pulled into chamber 420 or recess 428 of the cutting device. If pressure is applied too rapidly, the sharp cutting edge 414 of a cutter such as cutter 400 may dig into anvil 210 before anvil 210 can slide into a centered orientation. Accordingly, the use of a cutter with at least a recess at its cutting end and a spherical engaging end accommodates imperfections in the alignment of the cutter and the anvil. --

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Please replace the paragraph beginning at page ~~71~~, line 6, with the following rewritten paragraph:

-- After the opening is formed by cutter 400' then the vessels may be joined in the same way that a vessel is joined perpendicularly to a side of another vessel. For example, the portions defining the openings may be clipped or stapled together through the use of a clipping or stapling device 800 that delivers clips 810 or staples. If the vessels are mechanically joined through the use of sutures, staples or clips then it may be desirable to enhance the leak proof character of the anastomosis through the use of laser welding with a conventional laser welding device, such as an endoscopic laser welding devices. Similarly, the seal may be augmented through the appropriate use of biocompatible adhesives administered by conventional delivery devices, including endoscopic glue delivery devices. Additionally, a seal may be formed or strengthened by techniques such as laser soldering, including chromophore-enhanced laser soldering, and laser sealing. --

82 4 SM 6/16/06

Please replace the paragraph beginning at page ~~81~~, line ~~3~~, with the following rewritten paragraph:

-- As indicated above, anvil pull engager 500 has two primary components including an anvil pull holder 530 and anvil pull advancer 560. Anvil pull holder 530 receives anvil pull 230 via spring biasing device 450. More particularly, anvil pull 230 extends through cutter cup 458, rotatable spring housing 456, spring 460 and sleeve 462 around spring 460, and out of threaded jam screw 464. --

82 9 SM 6/16/06

Please replace the paragraph beginning at page ~~81~~, line ~~8~~, with the following rewritten paragraph:

-- Anvil pull holder 530 includes a holder mount 532 positioned in track 730 of body 710. In this embodiment, holder mount 532 is moveable so that the anvil pull can be advanced after it is held. However, in other embodiments, the anvil pull holder may just lock the anvil pull into position such that the cutter is moved against a stationary anvil. Similarly, the spring biasing device 450 may be eliminated so that the vessel is cut only by pressure exerted by the anvil pull against the cutter. As discussed above, while the cutter and the anvil may engage each other in these arrangements, it is preferable for the cutter to apply some pressure as the anvil pull is advanced against the cutter. --

82 17 SM 6/16/06

Please replace the paragraph beginning at page ~~81~~, line ~~16~~, with the following rewritten paragraph:

-- Holder mount 532 may be utilized in different ways to hold anvil pull 230. Holder 530 has a split cone 534 inserted into a tapered chamber 536 against a spring 538. Anvil pull 230 extends through apertures in holder mount 532, spring 538, split cone 534 and out of an aperture centered in holder knob 540. Holder knob 540 is threadably engaged by holder mount 532 such that rotation of holder knob 540 advances split cone 534 in tapered chamber 536 causing split cone to lock onto anvil pull 230. Holder mount 532 may be slotted at its distal end, as may holder knob 540. By aligning the slot (not shown) of holder knob 540 with the insert slot (not shown) of holder mount 532, anvil pull 230 can be bent so that it extends through both the holder knob slot and the insert slot. Holder knob 540 can then be rotated so that the bent portion of anvil pull 230 is rotated into one of the locking slots (not shown) that extend perpendicularly

from the insert slot. This securely locks anvil pull 230 into position. Anvil pull 230 can be locked through the use of slots instead of or in addition to the use of split cone 534 in tapered chamber 536. --

83 18  
SM 6/16/06

Please replace the paragraph beginning at page ~~82~~, line ~~16~~, with the following rewritten paragraph:

-- Since anvil pull holder 530 is moveable, it threadably engages rotatable lead screw 562 of anvil pull advancer. More particularly, lead screw 562 is threadably engaged by anti-backlash nut 550 which is fixedly attached to holder mount 532. Anti-backlash nut 550 has an attachment face 552 through which a plurality of attachment face screws 554 extend to hold holder mount 532 and anti-backlash nut 550 together. --

84 21  
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Please replace the paragraph beginning at page ~~83~~, line ~~20~~, with the following rewritten paragraph:

-- First plate engager 600a and second plate engager 600b each have a cutter aperture 620a and 620b, as shown in FIG. 6B. Cutter 400 extends through these aligned apertures 620a-b. First plate engager 600a is positioned on rail 640 such that it extends slightly beyond cutting edge 414 of cutter 400. This difference in length enables first compression plate 300a to be held slightly beyond cutter 400 in a manner that permits the wall of vessel 20 to be pulled into compression plate apparatus 300 as shown in FIG. 6D-6E and distended as needed. --